

## REMARKS

In the Office Action dated April 25, 2002, claims 1-10 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the reasons set forth in paragraphs 4 and 5 of the Office Action. In the reformulated claims, the Examiner's comments have been taken into account, and all claims of the application are submitted to be in compliance with all provisions of Section 112.

By the present Amendment, a new independent claim 15 has been submitted, which is a combination, with further editorial revisions of original claims 1, 2, 7 and 8. New independent claim 16 is a combination of original claims 1, 2 and 10, with certain editorial revisions, and new independent claim 23 is a combination of original claims 1, 2 and 3, with certain editorial revisions. Appropriate sets of dependent claims are presented with respect to each of these independent claims. Original independent method claim 14 has been amended, and original claims 11, 12 and 13 have been canceled.

Original claims 1-10 and 14 were rejected under 35 U.S.C. §102(e) as being anticipated Paltieli. Since all of the independent apparatus claims embody subject matter previously set forth in certain of the dependent claims, and since claim 14 has been retained in the application in amended form, the rejection based on the Paltieli reference is still relevant to the amended claims, and is respectfully traversed.

The Paltieli reference discloses a system having an ultrasound scanner 28, a biopsy needle 12 and a position acquisition unit 20. The position acquisition unit 20 includes an orientation sensor 30 arranged at the ultrasound scanner 28, and a further orientation sensor allocated to the biopsy needle 12. The position acquisition unit 20 identifies the position of the biopsy needle 12, and mixes an image of the biopsy needle into the ultrasound images acquired with the ultrasound scanner 30.

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in the Paltieli system, in the case of a 2D sector scan, a biopsy needle is mixed into the ultrasound image with a different color dependent on whether the biopsy needle is located in the plane of the 2D sector scan or outside of the plane of the 2D sector scan, or intersects the plane of the 2D sector scan. This is described in the Paltieli reference at column 5, lines 21-63. The Paltieli reference, however, does not provide any teaching to mix a designation of a distance of the biopsy needle from the image plane into the ultrasound image, as set forth in independent claim 15. The Paltieli reference, therefore, does not anticipate claim 15 or any of the ciaims depending therefrom.

Moreover, there is no teaching or suggestion in the Paltieli reference to provide such a distance designation. In column 8, lines 53-63 of the Paltieli reference, there is a teaching that the distances between the points of the dotted line that illustrates the biopsy needle in the ultrasound image provide a physician with information with respect to the angle that the biopsy needle exhibits with respect to the scan plane. This passage, however, does not teach or suggest mixing the tip of the biopsy needle into the ultrasound image and additionally mixing a designation of the distance of the tip of the biopsy needle from the plane of the ultrasound image into the image, in the event that the biopsy needle is located completely outside of the 2D sector scan.

As to independent claim 16, there is no disclosure in the Paltieli reference of identifying the position of a support mechanism for the patient using the same navigation system, which is used to identify the position of the biopsy needle. Claim 16 therefore is not anticipated by the Paltieli reference, nor are any of the dependent claims depending therefrom. Since there is no discussion in any form in the Paltieli reference of a support mechanism for the patient, it would not have been obvious to

a person of ordinary skill in the art to modify the Paltieli reference to additionally acquire the position of such a support mechanism, as set forth in claim 16.

Lastly, as to independent claim 23, there is no disclosure in the Paltieli reference of the biopsy needle having a flexible tip with a position sensor, as set forth in claim 23. Claim 23 therefore is not anticipated by the Paltieli reference, nor any of the claims depending therefrom. In view of the complete absence of any disclosure at all in the Paltieli reference with regard to an instrument with a flexible tip, it would not have been obvious to a person of ordinary skill in the art to modify the Paltieli system to include such a structure and/or to identify the position of such a flexible tip.

As to amended independent method claim 14, the Paltieli reference discloses the use of a "viewing device" at column 8, lines 32-68. The example given in the Paltieli disclosure is the use of 3D glasses in order to be able to visualize the biopsy needle and its trajectory in three dimensions. The Paltieli reference also refers to a computer program, which is intended to successively mix 2D images into the left lens of the glasses and into the right lens of the glasses. There is no disclosure or suggestion in the Paltieli reference, however, of a method wherein a 3D image of a first subject is intra-operatively acquired during an interventional procedure, while the image of a second subject, interacting with the first subject during the procedure, is mixed into the 3D image, also intra-operatively, by means of a navigation system, as set forth in claim 14.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is therefore respectfully requested.

Submitted by,

(Reg. 28,982)

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## **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

## IN THE CLAIMS:

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Claim 3 has been amended as follows:

3. (Amended) A system as claimed in claim [2] 15 wherein said navigation system includes identifiers, selected from the group consisting of detectable marks and position sensors, which are respectively attachable to said image signal acquisition unit and to said second subject and which are identifiable as to position by said position acquisition unit.

Claim 4 has been amended as follows:

4. (Amended) A system as claimed in claim [1] 15 wherein said image signal acquisition unit comprises an ultrasound probe.

Claim 5 has been amended as follows:

5. (Amended) A system as claimed in claim [1] 15 wherein said image signal acquisition unit comprises an X-ray source and an X-ray receiver.

Claim 6 has been amended as follows:

6. (Amended) A system as claimed in claim [1] 15 wherein said imaging unit produces a 3D image of said first subject from said image signals.

Claim 7 has been amended as follows:

7. (Amended) A system as claimed in claim [1]16 wherein said imaging unit products a 2D image of said first subject from said image signals.

Claim 9 has been amended as follows:

9. (Amended) A system as claimed in claim [1] 15 wherein said position acquisition unit simultaneously identifies the position of said image signal acquisition unit an the position of said second subject.

Claim 10 has been amended as follows:

10. (Amended) A system as claimed in claim [1] 15 further comprising an acceptance device for said first subject and wherein said position acquisition device identifies a position of said acceptance device simultaneously with identifying the position of said image signal acquisition unit and the position of said second subject.

Claim 14 has been amended as follows:

14. (Amended) A method for mixing an image of a second subject into an image acquired from a first subject, comprising the steps of:

intra-operatively acquiring [an] <u>a 3D</u> image of a first subject with an image signal acquisition unit <u>during an interventional procedure</u>;

determining a position of said image signal acquisition unit;

<u>intra-operatively</u> determining a position of a second subject <u>interacting with</u>

<u>said first subject in said interventional procedure;</u>

determining the position of said second subject relative to said image signal acquisition unit; and

intra-operatively mixing a representation of said second subject into said <u>3D</u> image of said first subject.

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